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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,572	02/11/2004	David Burton	24,577-45CIP	6003

7590 09/19/2007
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EXAMINER

ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3771

MAIL DATE	DELIVERY MODE
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09/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,572	Applicant(s) BURTON, DAVID	
	Examiner Shumaya B. Ali	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Status of Claims

Claims 1-31 are pending in the current application.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **cardiac pacemaker** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

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pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 14, 19, is objected to because of the following informalities: in line 3, the term "PTT" can have different meaning, therefore applicant is requested to write out what is considered PTT. Appropriate correction is required.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 22 been renumbered 23, thus claims 23-31 respectively renumbered as 24-32

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-15, 24,25, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Miles US 5,353,788..

As to claim 8, Miles discloses a gas delivery system comprising a mask (see labeled fig.2, attachment below) having at least one physiological sensor (col.4, lines 55-60) connected (col.4, lines 43-45) thereto; a gas delivery device (fig.2,1) having an adjustable gas delivery setting (gas delivery adjustment is possible via 12), and a processor (fig.2, 12) in communication with the gas delivery device and the sensor, the processor is adapted to determine the existence of a sleep disorder and to adjust the gas delivery setting based thereon (see col.5, lines 26 and 27, lines 48-50, and col.6, lines 17-24).

As to claim 9, Miles discloses sensor for abdominal and leg movement (see col.5, lines 55-57), thus discloses EMG sensor.

As to claim 10, Miles discloses sensor that detects heart rate (col.3, lines 55-60), thus discloses ECG sensor.

As to claim 11, Miles discloses blood oxygen saturation sensor, thus discloses SPO2 sensor (see col.4, lines 55-60).

As to claim 12, Miles discloses EEG sensor (see col.4, lines 55-60).

As to claim 13, Miles discloses the processor monitor physiological data, therefore the processor inherently adapted to determine patient arousal (see col.6, lines 17-30).

As to claim 14, Miles discloses a gas delivery system comprising a mask (see labeled fig.2 attachment below) having at least one EEG sensor (col.4, lines 55-60) connected thereto, a gas delivery device (fig.2,1) having an adjustable gas delivery setting (delivery is adjusted via a processor 12); a processor (fig.2, 12) is communication with the gas delivery device and the

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EEG sensor, the processor adapted to determine arousal and to adjust the gas delivery setting based thereon (see col.5, lines 26 and 27, lines 48-50, and col.6, lines 17-24).

As to claim 15, Miles discloses blood oxygen saturation sensor, thus discloses SPO2 sensor (see col.4, lines 55-60), and further discloses a sensor to detect heart rate, thus discloses an ECG sensor (col.3, lines 55-60) connected to the mask (col.4, lines 34-37). Miles further teaches a processor (fig.2, 12, col.5, lines 26 and 27, lines 48-50, and col.6, lines 17-24) that can inherently derive a PTT value from an output of each sensor.

As to claim 24, Miles discloses an apparatus comprising a mask (see fig.2 attachment below) having a body position sensor (see col.4, lines 55-60) attached thereto (see col.4, lines 33-37), a processor (fig.2, 12) in communication with the sensor and adapted to determine body position from the body position sensor's output (see col.5 lines 20-68, and col.6, lines 1-30).

As to claim 25, Miles discloses movement sensor (col.4, lines 55-60) attached to the mask (col.4, lines 33-37) and in communication with the processor and wherein the processor is adapted to determine movement from an output of the movement sensor (see col.5, lines 20-68, and col.6, lines 1-30).

As to claim 31, Miles discloses a gas delivery system comprising a gas mask (see fig.2 attachment below) adapted to fit on a patient, a gas delivery device (fig.2,1) having an adjustable gas delivery (via processor 12, see fig.2), and a processor (fig.2,12) in communication with the gas delivery device (see fig.2) and a cardiac pacemaker (processor inherently communicate with a pacemaker via heart rate sensor, see col.6, lines 55-60), the processor

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adapted to adjust the gas delivery based on a signal from the cardiac pacemaker (see col.5, lines 20-68, and col.6, lines 1-30).

As to claim 32, Miles discloses the processor receives an additional electrophysiological signal (plurality of sensors on mask, see col.4, lines 55-60) from the patient, and said processor determines the existence of a sleep disorder based upon the signals (see col.5, lines 20-68, and col.6, lines 1-30).

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Cui et al. US 5,584,296.

As to claim 21, Cui discloses a method of obtaining SPO2 (see blood oxygen in col.1, lines 62-64) reading from a mask (fig.2, 26) comprising attaching a light source (fig.2, 36) and a light sensor (fig.2, 32) on a mask so that the light source and light sensor are positioned to contact a person's forehead (see fig.1), illuminating the light source (col.2, lines 63-66); detecting light from the light source (via 32,34) as it deflects from the person's skull; and converting (via 20, see fi.1) the detected light into an analog signal.

As to claim 22, Cui discloses high pass filtering the analog signal (using).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles US 5,353,788.

As to claim 17-20, Miles discloses a mask with various physiological sensors (col.4, lines 55-60) that can determine arousal, a CPAP equipment that provides a supply of gas to a patient (col.3, lines 65-68), a processor that communicates with those sensors (col.5, lines 25-68, and col.6, lines 1-30), which is capable of calculating PPT and cortical and subcortical signal. Although Miles lacks the detailed method steps cited for claims 17-20, Miles' device however has structures, which are fully capable of providing the method steps as cited. Therefore, the method steps as cited for claims 17-20 would have been obvious result of using the device of Miles.

Claims 1, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles US 5,353,788 in view of Genger et al. WO00/66209 (note: US 7,054,680 B1 is the rejection for translation purpose).

As to claims 1, Miles discloses a mask assembly (3,26) comprising a body (see fig.2, attachment below) having an internal surface (see fig.2, mask inherently have external and internal surface), an external surface (see fig.2, attachment below), and a perimeter surface (see fig.2 attachment below); and a forehead support (see fig.2 attachment below) connected to the body. Miles further discloses EEG sensor (see col.4, lines 55-59). Miles however lacks the forehead support having an EEG sensor (see col.4, lines 44-45; lines 55-59). However, Genger teaches a forehead support bar with sensor that reads brain activity (see fig.1, 9/10/11; see col.1, lines 20-22). Applicant's EEG sensor also detects brain activity. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles to

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change the location of the EEG sensor for the purposes of detecting electrical potential on a patient with an electrode device which can be applied in the forehead as taught by Genger (see col.1, lines 45-50).

As to claim 27, Miles discloses the claimed invention as applied to claim 1.

As to claim 28, Genger teaches forehead support pad (see fig.4, 8).

As to claim 29, Miles discloses a movement sensor (see col.4, lines 55-60).

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles as modified by Genger and in view of Kwok US Patent No. 6532961 B1

As to claims 2 and 3, Miles lacks padding and forehead support bar, however mask with such features are well known in the art. Kwok teaches padding (25) and forehead support bar (12). Therefore, it would have been obvious to one of ordinary skills in the art at the time of the invention to modify Miles for the purposes of providing cushioning to the forehead using padding and enhance strap attachment with comfort around the forehead as taught by Kwok (see Kwok col.4 lines 15-20, and 40-45).

Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles as modified by Genger and Kwok and in view of Cui et al. US Patent No. 5,584,296.

As to claim 4, Miles lacks an SPO2 sensor is located on the forehead support bar. However, Cui teaches that the blood oxygen saturation sensor, hence SPO2 can be located human skull ("forehead") for monitoring internal brain tissue (see col.1, lines 66-68 and lines 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention is made to locate SPO2 sensor on the forehead support bar of Genger for the purposes of monitoring internal brain tissue as taught by Cui.

Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles, Genger, Kwok, Cui, and in view of Droussseau US Patent No. 6,708,051 B1.

As to claim 5, Miles as modified lacks sensor includes a pad comprised of a conductive carbonized rubber material. However, Droussseau teaches carbonized plastic or conductive plastic electrodes in connection with carbon lead wires can be used to limit the susceptibility of his system to physiological and electronically induced contamination (see col.2, lines 33-36). Therefore, it would have been obvious to one of ordinary skill in the art the time the invention was made to modify Miles in order to provide a pad with conductive carbonized rubber material for the purposes of limit the susceptibility of the sensor to physiological and electronically induced contamination as taught by Droussseau.

As to claim 7, Droussseau teaches a portion of the conductive material is adapted to measure EOG (col.1, lines 20-25).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles, Genger, and in view of Brown.

As to claim 6, Miles discloses a strap extending from the mask (see labeled fig.2 attachment below) and physiological sensors (see col.4. lines 33-35, lines 44-45; lines 55-59; col.5 lines 615, and col.7 lines 37-51), however, lacks said sensor is located on the strap. However, Brown teaches physiological sensors can be located on the strap (see fig.1f, 33). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles to change the location of the physiological sensor because it is known in the art as taught by Brown.

Claims 16 and 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles and in view of Brown.

As to claim 16, Miles discloses sensors that detect abdominal and leg movements (see col.4, lines 55-60), thus teaches EMG sensor that is located on mask (see col.4, lines 34-37). Miles however lacks sensors located on strap. However, Brown teaches physiological sensors can be located on the strap (see fig.1f, 33). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles to change the location of the physiological sensor because it is known in the art as taught by Brown.

As to claim 23, Miles discloses a method of detecting oral or nasal breathing during nasal ventilation, the method comprising providing a mask adapted to form a seal between a patient's nose and mouth (seal is provided by straps, see fig.2 attachment below), the mask inherently having an interior surface and an exterior surface, the mask also having a first thermal sensor (see col.4, lines 55-60) on the interior surface (see col.4, lines 33-37) and a second thermal sensor (see col.4, lines 33-37). Miles however does not disclose the thermal sensor is located on the exterior surface to be adjacent the patient's mouth. Brown however teaches thermal sensor can be located on strap (see fig.1f, 33). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles to change the location of the physiological sensor because it is known in the art as taught by Brown. Miles further discloses detecting a temperature change (via processor 12, see fig.2) in the first or second thermal sensor (see col.5, lines 20-68, and col.6, lines 1-30). Thus, it would have been obvious to obtain the method steps of claim 22 using the device of Miles as modified by Brown.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tripp, Jr.

US H1039

As to **claim 26**, Tripp discloses a method of detecting a leak (col.1, 46-53) in a breathing mask (106) providing a mask (106) having a perimeter surface with a plurality of thermally conductive surface distributed though out the perimeter surface (sensors 132, 133, 138, 140, 210, 212, 226, and 228). Tripp however is silent on method step of detecting a temperature change in any of the plurality of thermally conductive surface. However, Tripp teaches an electronic processing circuitry (see col.3, liens 6-9) which is considered to detect the temperature changes in any of the plurality of thermally conductive surface. Therefore, the method steps cited for claim 25 would have been obvious over using the apparatus of Tripp.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miles as modified by Genger et al. WO00/66209 (note: US 7,054,680 B1 is the rejection for translation purpose) and in view of Tripp H1039.

As to **claim 30**, Miles lacks a mask seal leakage detector. However, Tripp teaches perimeter surface of a mask is adapted to sense air leaks (see col.11, lines 46-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Miles in order to include a leakage detector for the purposes of detecting air passing between the mask and the external environment as taught by Tripp.

Response to Arguments

Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection.


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Shumaya B. Ali
Examiner
Art Unit 3771


JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
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9/14/07

Art Unit: 3771

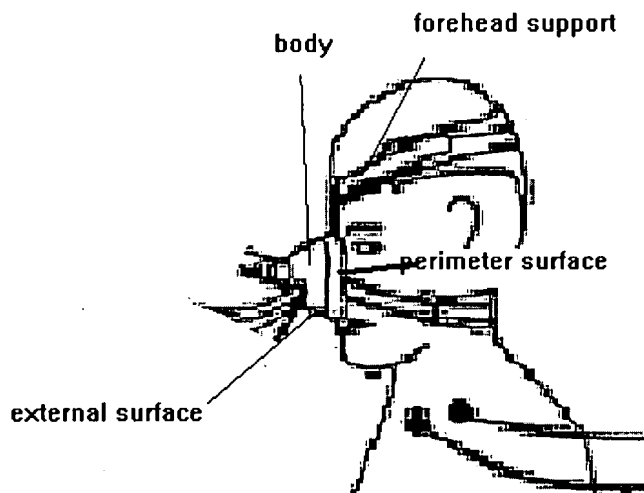


Figure 2

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